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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/729,026

12/05/2003

Steven F. Bolling

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09/06/2005

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EXAMINER

LAYNO, CARL HERNANDZ

ART UNIT

PAPER NUMBER

3762

DATE MAILED: 09/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/729,026	<b>Applicant(s)</b> BOLLING ET AL.	
	<b>Examiner</b> Carl H. Layno <i>Carl H. Layno</i> 8/31/05	<b>Art Unit</b> 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 16 August 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 7 and 9-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 7, 9 and 15-23 is/are allowed.
- 6) ☒ Claim(s) 11, 12, 14, 26, 27 and 32 is/are rejected.
- 7) ☒ Claim(s) 10, 13, 24, 25 and 28-31 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>8/16/05</u> | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. Acknowledgment is made of applicant's amendment, which was received by the Office on August 16, 2005.

2. Claims 1-6, and 8 are canceled. Claims 20-32 have been added. Claims 7 and 9-32 are active.

#### ***Continued Examination Under 37 CFR 1.114***

3. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 16, 2005 has been entered.

#### ***Information Disclosure Statement***

4. Acknowledgment is made of applicant's Information Disclosure Statement (PTO-1449), which was received by the Office on August 16, 2005.

#### ***Claim Rejections - 35 USC § 102***

5. Upon further reconsideration of applicant's amendments to the claims and claim cancellations, the Examiner is withdrawing the 35 U.S.C 102(b) rejection of Aldea '957

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(Applicant's prior art), which was made against claims 4, 7, 8, 10, 11, and 13 in the last Office action.

6. Having reviewed applicant's most recently cited prior art documents (i.e. the PTO-1449 of August 16, 2005), the Examiner has discovered a reference which forms the basis of the following new art rejection.

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 11, 12, and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by the Verkerke et al article: "The PUCA Pump: A Left Ventricular Assist Device (cited by Applicant).

The Verkerke et al article: "The PUCA Pump: A Left Ventricular Assist Device, recently cited by Applicant, describes the details of a pulsatile catheter (PUCA) pump for assisting a patient's cardiac output. The pump (Fig.1) is capable of pumping blood at 3 liters/minute (p.365, Abstract, col.2, line 8). This meets applicant's definition of a subcardiac flow rate of 0.1-3 liters/minute (p.15, paragraph [0051], line 5, of applicant's specification). The catheter associated with the pump is inserted through either the femoral or proximal brachial artery and positioned in the left ventricle via the aorta (p.365, right column, bottom paragraph). Blood flows in both directions within the catheter during aspiration (Fig.1A) and during ejection (Fig.1B)

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from the left ventricle to the aorta. The catheter is made of polyethylene (p.366, left column, 3<sup>rd</sup> paragraph), a flexible plastic.

9. Claims 14, 26, and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by the Ide et al article: "Hemodynamic Evaluation of a New Left Ventricular Assist Device: An Integrated Cardioassist Catheter as a Pulsatile Left Ventricle-Femoral Artery Bypass" (cited by the Applicant).

The Ide et al article "Hemodynamic Evaluation of a New Left Ventricular Assist Device: An Integrated Cardioassist Catheter as a Pulsatile Left Ventricle-Femoral Artery Bypass", which was recently cited by the applicant as prior art, describes a pumping system (Fig.1) for pumping blood from a patient's left ventricle to the femoral artery using a number of different pumps. The flow rates of these pumps (i.e. IABP and ICAC) appear to be between 1.27 and 1.55 liters per minute (Fig.3), which is within applicant's definition of subcardiac flow rates (i.e. 0.1-3 liters/minute -- p.15, paragraph [0051], line 5, of applicant's specification). The catheter from the blood pump to the left ventricle is a double lumen catheter, which is capable of reverse flow counterpulsation (Fig.1). The centrifugal pump, shown in Fig.1, is considered to be a rotary pump.

***Allowable Subject Matter***

10. Claims 10, 13, 24, 25, and 28-31 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

11. Claims 7, 9, and 15-23 are allowed.

12. The following is a statement of reasons for the indication of allowable subject matter:

Independent claim 9, as amended, recites details of a system for supplementing blood circulation in a patient including many elements, among them a first cannula and a second cannula positioned between the pump and first and second lumens, respectively. Having conducted numerous searches, the examiner was unable to find these features in combination with all of the other claimed features of applicant's pumping system; consequently, the Examiner deems this claim and depending claim 7 to be allowable.

Independent claim 15 also describes details of a system for supplementing blood circulation including a conduit, capable of reverse flow, configured to direct blood from a "first peripheral vessel" to a "second vessel". Though the prior art references of Ide et al, Verkerke et al, and Aldea all recite heart pumping systems capable of reverse flow counterpulsation, none of these teaches directing blood from a "first peripheral vessel" to a "second vessel". Instead, these references direct blood flow to or from chambers within a patient's heart. In view of this difference, the Examiner also deems claim 15 and its depending claims to be allowable.

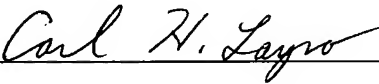
### *Conclusion*

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carl H. Layno whose telephone number is (571) 272-4949. The examiner can normally be reached on 9/4/5.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



CARL LAYNO  
PRIMARY EXAMINER

CHL  
8/31/2005